

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/630,206	AOKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chih-Min Kam	1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/13/07.
  2. ☒ The allowed claim(s) is/are 1,4,5,9,12,13,31 and 32.
  3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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## DETAILED ACTION

### *Status of the Claims*

1. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are pending.

Applicants' amendment filed November 13, 2007 is acknowledged, and applicants' response has been fully considered. Thus, claims 1, 4, 5, 9, 12, 13, 31 and 32 are examined.

### *Withdrawn Claim Rejections - Obviousness Type Double Patenting*

2. The previous rejection of claims 1, 4, 5, 9, 12, 13, 31 and 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U. S. Patent 6,869,610, is withdrawn in view of applicants' submission of a terminal disclaimer, and applicant's response at page 4 in the amendment filed November 13, 2007.

### *Examiner's Amendment*

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Taffy on December 21, 2007.

#### **Examiner's Amendment to the Specification:**

Please replace the paragraph after the subtitle "CROSS REFERENCE" of the specification in the preliminary amendment filed July 29, 2003 with the following paragraph:

This application is a continuation of application serial number 10/199,222, filed July 18, 2002, now U.S. patent no. 6,869,610, which is a continuation of serial number 09/550,371, filed April 14, 2000, now U.S. patent no. 6,464,986 B1, the entire contents of which prior application and patent are incorporated herein by reference in their entireties.

**Examiner's Amendment to the Claims:**

Claim 31 has been amended as follows:

31. (Currently amended) A method for treating a face pain, the method comprising the step of peripheral, intramuscular administration to a patient of a therapeutically effective amount of a botulinum toxin to a region of a face pain not due to a headache, wherein the face pain is not associated with a muscle disorder, thereby alleviating the pain in the face.

**The following is an Examiner's Statement of Reasons for Allowance:** The following reference appears to be the closest art to the claimed invention. Aoki et al. (U. S. Patent 6,869,610) teach a method for alleviating neuralgia, comprising peripheral administration of a therapeutically effective amount of a botulinum toxin to a human patient, wherein the pain is not associated with a headache, and the neuralgias include herpetic neuralgia, trigeminal neuralgia and other neuralgias. It is known that trigeminal neuralgia is a facial pain typically near the nose, lips, eyes or ears. Thus, the patent discloses a method of treating a face pain such as trigeminal neuralgia by peripheral administration of a botulinum toxin to a mammal, and a terminal disclaimer was filed in the instant application over the 6,869,610 patent. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

December 21, 2007